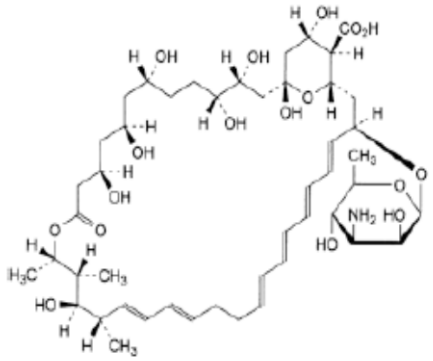
PRODUCT INFORMATION

MYCOSTATIN® ORAL DROPS
(Nystatin)

Name of the medicine

Nystatin is an antifungal substance obtained by fermentation using certain strains of *Streptomyces noursei* as the production micro-organism. It contains mainly tetraenes, the principal component being nystatin A1.

Nystatin is a yellow or slightly brownish powder, hygroscopic. Practically insoluble in water. Freely soluble in dimethylformamide and in dimethyl sulfoxide. Slightly soluble in methanol. Practically insoluble in alcohol.



$C_{47}H_{75}NO_{17}$ CAS *1400-61-9*

Description

Mycostatin Oral Drops is a bright yellow cherry flavoured suspension containing the active substance nystatin 100,000 IU/mL. It also contains Bentonite, sodium calciumedetate, Sucrose, Methyl and Propyl hydroxybenzoates, Polysorbate 80, Cherry flavour F-1242, quinoline yellow (104) and Water - purified.

Pharmacology

Nystatin is an antifungal antibiotic, active against yeasts and yeast like fungi, including *Candida albicans*. The antifungal activity is probably due to the binding of sterols in the cell membrane of the fungus with a resultant change in membrane permeability allowing leakage of intracellular components.

Pharmacokinetics

Nystatin is poorly absorbed from the gastrointestinal tract after oral administration.
It is not absorbed through the skin or mucous membrane when applied topically.

Indications

Treatment of candidal infections of the oral cavity caused by *candida albicans.*

Contraindications

Known hypersensitivity to nystatin or any of the other ingredients in the formulation (See 'Description').

Precautions

Mycostatin Oral Suspension should not be used for the treatment of systemic mycoses.
If irritation or sensitization develops, treatment should be discontinued.

If there is a lack of therapeutic response, appropriate microbiological studies (e.g. KOH smear and/or cultures) should be repeated to confirm diagnosis of candidiasis and rule out other pathogens before instituting another course of therapy.

Carcinogenesis, Mutagenesis, Impairment of Fertility
No long-term animal studies have been performed to evaluate the carcinogenic potential of nystatin.
No studies have been performed to determine the mutagenicity of nystatin or its effect on male or female fertility.

Use in immunocomprimised patients
Higher doses, for example 500,000 units 4 times daily, may be needed. However, the use of alternate antifungal antibiotics is preferred for the treatment of oral thrush in patients with immunosuppression.

Use in pregnancy. (Category A)
Animal reproduction studies have not been conducted with Mycostatin oral suspension. It is also not known whether Mycostatin oral suspension can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Mycostatin oral suspension should be prescribed for a pregnant woman only if the potential benefit to the mother outweighs the potential risk to the fetus.

Use in lactation
It is not known whether nystatin is excreted in human milk. Though gastrointestinal absorption is insignificant, caution should be exercised when nystatin is prescribed for a nursing woman.

Interactions with other medicine

Nylstatin is not known to interact with other medicines.

Adverse reactions

Mycostatin Oral Drops is well tolerated by all age groups, even with prolonged administration. Large doses have occasionally produced diarrhoea, gastrointestinal distress, nausea and vomiting. Rash, including urticaria, has been reported rarely. Stevens-Johnson syndrome has been reported very rarely. Hypersensitivity and angioedema, including facial oedema, have been reported.

Dosage and administration

Shake well before use.

DOSAGE: Children and Adults: 1 mL 4 times daily. The drops should be held in the mouth and swirled around for as long as possible, before swallowing. Continue treatment for 48 hours after symptoms have subsided.

If signs and symptoms worsen or persist (beyond 14 days of treatment), the patient should be re-evaluated, and alternate therapy considered.

Overdose

Oral doses of nystatin in excess of 5 million units daily have caused nausea and gastrointestinal upset.

For current treatment of overdosage, contact the Poisons Information Centre on 13 11 26 immediately.

Presentation

Oral drops containing Nystatin 100,000 IU/mL in bottle glass pack size of 24mL.

Poisons Schedule

S3 – PHARMACIST ONLY MEDICINE.

Sponsor

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Approved by the Therapeutic Goods Administration 05 September 2012